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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,451	03/07/2002	Ernst Bernhard Grabitz	205,360	4546

7590 03/10/2006

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EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,451

Applicant(s)

GRABITZ, ERNST BERNHARD

Examiner

Dr. Kailash C. Srivastava

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37.CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's response and amendment filed 12 December 2005 to Office Action mailed 10 August 2005 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

2. To ensure that all papers filed in a response remain together and for expedient communication to a response /amendment filed to an Office Action, Examiner will very much appreciate that applicants in the header for said response label each page with application Serial number and Attorney's Docket number. This practice immensely facilitates examination of an application/response.

3. In view of applicants' remarks and amendments filed 12 December 2005 to Office Action mailed 10 August 2005, Examiner herewith withdraws following objections/rejections:

- Objection to Claims 36 and 43-48;
- Rejection to Claims 34-49 under 35 U.S.C. §112, second paragraph;
- Rejection to Claims 34-48 drawn to a method and Claim 49 drawn to a composition as anticipated by Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al (eds. PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pgs. 836-839) or in the alternative, under 35 U.S.C. § 103(a) as obvious over combined teachings of Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al (eds. PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pgs. 836-839) in view of Sagar et al. (WO 94/22572)

In the Office Action mailed 10 August 2005.

### **CLAIMS STATUS**

4. Claims 1-49 have been cancelled.

5. Claims 50--70 have been added.
6. Claims 50-70 are pending and are examined on Merits

### **Claims Objection**

7. In view of applicant's amendment filed 12 December 2005, following is an objection to newly filed Claims 50, 58-60 and 64-70.
8. Claims 50-51, 58-60 and 64-70 are objected to for the following reasons:
  - Claims 66-69 are objected to because at Line two of each one of the cited Claims, in between the words "polyphenolic" and "hydrophilic" a ", " should be inserted.
  - Claims 50, is objected because of the recitation, "empty microorganism" in Claim 50 (ii). Even after the endocellular contents of said microorganism are withdrawn by any process of leakage, the space within the confines of left over microbial cell envelope is not empty because it is filled with air, otherwise the cell envelope remaining after the withdrawal/ leakage of the endocellular contents will collapse.
  - The recitation, "inactivated microorganism" in Claim 50(iii) or "microorganism" in Claims 51, Claim 58, Lines 4 and 6, Claim 59, Line 2 and each of Claims 66-70 is objected to because after the endocellular contents of said microorganism are withdrawn, only the cell envelope is left which does not comprise a microorganism. Said cell envelope is comprised of Cell membrane or plasmalemma and the cell wall. Furthermore, even after said cell envelope is filled with a pharmaceutical/nutrient/ neutraceutical it is not a microorganism because it is not comprised of same matter as a microbial cell. Therefore to label a leaked out microbial cell where only the cell envelope is left as "microorganism" is inappropriate.

- The recitation “or a mixture thereof” at Claim 50 (iii), Lines 3-4, Claim 58, Line 7 is objected to because depending on the concentrations of solute in the respective isotonic and/ or hypotonic solution, the resultant solution will still remain either hypotonic or isotonic. Not mixed hypotonic and isotonic.
- Phrase, “hypertonic treatment in step i) is obtained by incubation of a hypertonic solution comprising NaCl” is objected to because said phrase does not clarify that the microbial cell is incubated with or in a hypotonic solution comprising NaCl”.
- At line 1 of each of claims 64-65 a --, -- should be inserted after the recitation, “wherein”.

Appropriate corrections are required.

### ***Claim Rejections - 35 U.S.C. § 103***

9. In view of applicants' amendment filed 12 December 2005, following is an objection to newly filed Claims 50-70 under 35 U.S.C. § 103 (a).
10. Claims 50-70 are rejected under 35 U.S.C. § 103 (a) as obvious over Combined teachings from Pannell (U.S. Patent 5,288,632) in view of Sagar et al. (WO 94/22572).

Pannell's invention teaches materials that are encapsulated in a *Saccharomyces* cell (i.e., a microbial cell or microorganism). Said method comprises a grown intact microbe harvested and subsequently, materials such as eucalyptus oil and vitamins (e.g., A and C) or other compounds are encapsulated in said microbe through mixing the microbe with liquid forms of those materials. Said composition, i.e., *Saccharomyces cerevisiae* cells encapsulating bioflavonoid and vitamins are then separated from the reaction mixture comprising liquid forms of

said nutrient and the microbial cell through centrifugation and subsequently freeze-dried (Column 2, Lines 26-66; Column 3, Lines 31-57; Column 4, Lines 55-62 and Column 6, Lines 40-49). Pannell intrinsically teaches removing the endocellular material from said *microbial* cell, because in order for said nutrients/ bioflavonoids to be encapsulated in to said microbial cell, the endocellular material from said microbial cell has to leak, otherwise said nutrients will not be able to get in to the cell. Pannell, however, does not teach  $\alpha$ -tocopherol encapsulated in said biocapsules.

Sagar et al. teach an animal feed composition for each stage of growing fish larvae, said animal feed comprising inactivated yeast cells (i.e., biocapsules), wherein nutrients such as fish oil are encapsulated in said inactivated yeast cells. Fish oil inherently comprises  $\alpha$ -tocopherol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pannell's teachings with Sagar et al. to incorporate different nutrients in said inactivated *Saccharomyces cerevisiae* (i.e., microorganism) cells (i.e., biocapsule), because both the prior art references teach compositions comprising inactivated microorganism, wherein nutraceuticals have been encapsulated in said inactivated microbial cells. Sagar et al. remedy deficiencies in Pannell's teachings, because Sagar et al. teach a yeast biocapsule and incorporating in said biocapsule  $\alpha$ -tocopherol as fish oil.

One having ordinary skill in the art would have been motivated to modify Pannell's teachings with those of Sagar et al. to incorporate different nutrients (i.e., bioflavonoids, vitamins, amino acids and oils) in said microbial biocapsule, because the prior art references teach steps of inactivating a microorganism (i.e., *Saccharomyces cerevisiae*) and encapsulating nutrients (e.g., vitamins, bioflavonoids and  $\alpha$ -tocopherol) in an inactivated microorganism cell to produce compositions comprising inactivated yeasts, wherein antibacterial compounds or nutrients, or nutraceuticals have been encapsulated in inactivated yeast cells.

(Column 2, Lines 26-66; Column 3, Lines 31-57; Column 4, Lines 55-62 and Column 6, Lines 40-49). Sagar et al. remedy deficiencies in Pannell's teachings of incorporating other nutrients (e.g.,  $\alpha$ -tocopherol) in said inactivated *Saccharomyces cerevisiae* (i.e., microorganism) cells (i.e., biocapsules) (Page 1, Lines 8-9; Page 3, Lines 9-24 and Page 4, Lines 4-15).

None of the prior art references cited above teach incorporating oxytetracycline or sulfadimethoxine as an antibacterial compound/ antibiotic in their composition. However, the adjustment of particular conventional working conditions (e.g., choice of an antibiotic or substitution of an antibacterial compound with another antibacterial compound having same functional effect) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the cited prior art references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants are also advised that as admitted by the applicants on record Claims 66-70 are product by process claims. Product-by-process claims in the instantly claimed are not limited to the manipulations of the recited steps, only the structure implied by the steps. According to MPEP§2113, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). In instant invention,

as demonstrated in the discussion *supra*, an inactivated microbial cell encapsulating nutraceuticals and/or pharmaceuticals are well documented in the cited prior art.

### ***Claim Rejections Under 35 U.S.C. § 112***

#### ***Second Paragraph Rejections***

11. In view of applicants' amendment filed 12 December 2005, following is an objection to newly filed Claims 50-70.

12. Claims 50-70 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Newly presented Claims 50-70 in the current form are confusing and unclear. Applicants have to write the claims clearly to point out the subject matter that is applicants' invention. In rewriting, said Claims, however, applicant should ensure that no new matter is added.
- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The recitation, "inactivated microorganism" in Claim 50(iii) or "microorganism" in Claims 51, Claim 58, Lines 4 and 6, Claim 59, Line 2 and each of Claims 66-70 is not an art-recognized definition of a microorganism. Thus is because after the endocellular contents of a microbial cell are withdrawn or are leaked out only the intact cell envelope remains. The art recognized terminology for said item is a "ghost cell" or "Cell envelope without the cytoplasm". The examiner suggests that the applicant replace the term "microorganism in Claim 50(iii) or "microorganism" in Claims 51, Claim



58, Lines 4 and 6, Claim 59, Line 2 and each of Claims 66-70 with an art-recognized term.

- Recitation, “suitable “ in claim 52 is unclear and indefinite. It is not clear how one can determine with clarity and accuracy when the microorganism is suitable and what may be a suitable microorganism for one may not be suitable for another. Applicant is advised to define the metes and bounds for the term “suitable microorganism”.
- Claim 57 is rendered vague and indefinite by the use of parentheses. The use of parentheses encompassing terminology in the claims is indefinite because it is unclear if what is stated within the parentheses is a further limitation or simply alternative meaning.
- The recitation “obtainable” renders Claims 66-70 indefinite because this recitation in and by itself denotes a futuristic event. The metes and bounds of the claimed subject matter are not clearly defined. The examiner suggests that applicants should consider the recitation, “obtainable” in Claims 66-70 or define the metes and bounds of the term, “obtainable”.

All other claims depend directly or indirectly from the rejected claim (s) (e.g., 50) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### CONCLUSION

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

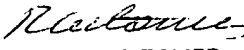
14. For the aforementioned reasons, no claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0926 Monday through Friday between 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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March 5, 2006